REMI SCIENCES
REGENERATIVE ENGINEERED MATERIAL INNOVATIONS

510 k SUMMARY K081025

Date of preparation: 11/11/08

NOV 21 2008

Applicant:
REMI SCIENCES INC
1400 Civic Place, Suite 225
Southlake, Texas76092

Telephone: (817) 506 –0835
Fax: (817) 608-9403
Contact: Sanjiv H.Naidu

DEVICE NAME:	Wrist joint ulnar (hemi-wrist) prosthesis
DEVICE TRADE NAME:	Isoclastic U™
DEVICE CLASSIFICATION:	Class II
PREDICATE:	SBI Uhead Implant, Silastic Swanson Ulnar Head Implant

DEVICE DESCRIPTION:

The IsoelasticU ulnar head implant allows for replacement of the distal ulnar head much like the predicate metallic and silicone elastomer distal ulnar head implants.

INDICATIONS FOR USE:

The **IsoelasticU™** is indicated for joint replacement arthroplasty of the ulnar head at the distal radioulnar joint (DRUJ) for the following indications

- Rheumatoid arthritis with or without tendon ruptures
- Degenerative arthritis or post traumatic arthritis
    - 1. Arthrofibrosis of the DRUJ
    - 2. Reconstruction of the distal ulna post tumor resection
    - 3. Failed Ulnar Head Resection
    - 4. Distal ulna instability with xray or bone scan evidence of arthritic or inflammatory changes
    - 5. Revision following failed ulnar head arthroplasty

Ulna stems are intended for uncemented use

REMI Sciences, Inc.
1400 Civic Place, Suite 225
Southlake, Texas 76092

ph 817-608-9400 ext.1600
fax 817-608-9403
cell 214-641-5171

sanj@remisciences.com
www.remisciences.com

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Comparison to the Original Predicate Device:

IsoelasticU is substantially equivalent to the legally marketed SBI Small Bone Innovations U head implant.

Regulatory Class:II

CATEGORY	REMI ISOELASTIC U	SBI UHEAD
Name	IsoelasticU	Uhead
Use	Single Use	Single Use
Fixation	Press fit stem	Press fit Stem
Material	UHMWPE/CpTitanium	Co-Cr/CpTi
Sizes	19Head/9stems	8head/4stem
Indications for use	- Rheumatoid arthritis with or without tendon ruptures - Degenerative arthritis or post traumatic arthritis 1. Arthrofibrosis of the DRUJ 2. Reconstruction of the distal ulna post tumor resection 3. Failed Ulnar Head Resection 4. Distal ulna instability with xray or bone scan evidence of arthritic or inflammatory changes 5. Revision following failed ulnar head arthroplasty	Is intended for replacement of the DRUJ following ulnar head resection arthroplasty: replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic disabilities presenting the following: pain and weakness of the wrist joint not improved by conservative treatment instability of the ulnar head with xray evidence of dorsal subluxation and erosive changes and failed ular head resection

Summary: Similarities of REMI Isoelastic U and SBI U head lies in the fact that they are both modular implants intended for use with press fit stems. Both the devices are intended for single use for implantation longer than 30 days. Both devices are made of standard industry materials with similar sizes and same indications.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

REMI Sciences, Inc.
% Sanjiv H. Naidu, M.D., Ph.D.
Chief Medical Officer
1400 Civic Place, Suite 225
Southlake, Texas 76092

NOV 21 2008

Re: K081025
Trade/Device Name: Isoelastic U™
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: Class II
Product Code: KXE
Dated: November 1, 2008
Received: November 6, 2008

Dear Dr. Naidu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510 (K) Number: K081025

Device Name: IsoelasticU™
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The **IsoelasticU™** is indicated for joint replacement arthroplasty of the ulnar head at the distal radioulnar joint (DRUJ) for the following indications

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  - 5. Revision following failed ulnar head arthroplasty
- Ulna stems are intended for uncemented use

Prescription Use___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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